REMARKS / ARGUMENTS

In the specification, the paragraphs have been amended to remove embedded hyperlinks as requested by the Office Action. No new matter has been added by way of amendment to the specification.

Reconsideration of the present application is respectfully requested. Claims 1, 2, 6, 21, 40, 41, 44, and 45 remain in this application.

Claims 1, 2, 6, 21, 40, and 41 have been amended. Support for the amendments resides throughout the specification and in the claims as originally filed. No new matter has been added by way of amendment to the claims.

It is respectfully requested that the amendments be entered.

Rejections under 35 U.S.C. §112

Rejections under 35 USC §112, second paragraph

Claims 1, 21, 40-41, and 44-45 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action states: "In claims 1, 2, 21, and 40, the phrase 'and that drives expression in' should be changed to 'and that drives expression of'.

Claims 1, 2, 21, and 40 have been amended to incorporate the Examiner's suggestion. Accordingly, this rejection should be withdrawn.

The Office Action asserts: "In claims 1, 21, 44, and 45, the metes and bounds of 'functional fragments' has not been defined. It has not been specified what is the function of the fragment, nor has Applicant described all the possible fragments which are being claimed."

Claims 1, 21, 44, and 45 have been amended to delete the word "functional".

The term "fragments" is extensively defined and described in the specification beginning on page 9, line 31 which reads: "Sequence *fragments* with high percent identity to the sequences of the present invention also refer to those fragments of a particular regulatory element nucleotide sequence disclosed herein *that operate to*

promote the seed-preferred expression of an operably linked isolated nucleotide sequence". And again on page 10, beginning on line 15: "Such sequences encompass fragments capable of driving seed-preferred expression, fragments useful as probes to identify similar sequences, as well as elements responsible for temporal or tissue specificity." It is believed one of skill in the art, upon reading the specification, would be well apprised of the metes and bounds of claims 1, 21, 44, and 45.

It is respectfully submitted that the specification is not required to disclose all possible permutations defined by the limitations of claims 1, 21, 44, and 45. The specification *is* required to provide sufficient disclosure and enablement so that one skilled in the art could make the embodiments encompassed by the claims. Accordingly, this rejection should be withdrawn.

The Office Action further states: "Claim 6 is indefinite in the recitation 'comprises a nucleotide sequence set forth in SEQ ID NO:1'. The indefinite article 'a' signifies more than one possible nucleotide sequence. Amending the claim to recite 'comprising the nucleotide sequence of SEQ ID NO:1' will obviate the rejection."

While the Examiner's point is well taken, it is believed the formal requirement for proper antecedent basis must be met by the use of the word "a". Claim 6 is an independent claim and there is no phrase to provide "*the* nucleotide sequence" with the necessary antecedent basis. Accordingly, this rejection should be withdrawn.

The Office Action further asserts: "Claims 1, 2, 21, and 40 are indefinite in the recitation 'maize Jip1'. The promoter maize Jip1 has not been specifically defined. Amending the claims to recite 'maize Jip1 of SEQ ID NO:1' will obviate the rejection.

The rejection is respectfully traversed. The full phrase of the rejected claims reads: "....drives expression of DNA *coding for* maize Jip1..." referring to the maize Jip1 coding region, not the promoter. Therefore the Examiner's suggested change would not clarify the claim, but rather would render it indefinite. Accordingly, this rejection should be withdrawn.

Rejections under 35 USC §112, first paragraph

Claims 1, 21, 40-41, and 44-45 are rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Office Action asserts: "The inventors claim an isolated promoter comprising a functional fragment of the nucleotide sequence set forth in SEQ ID NO:1.... The Applicants do not identify structural features unique to a maize Jip1 promoter that would define or describe 'functional fragments' of DNA that differ from SEQ ID NO:1, yet retain the maize Jip1 spatial and temporal expression pattern.... Since a maize Jip1 promoter has not been described by specific structural features or by specific function, the specification fails to provide an adequate written description to support the claims directed to 'functional fragments' of SEQ ID NO:1."

Claims 1, 21, 44 and 45 have been amended to delete the word "functional".

Specific structure for fragments is disclosed by SEQ ID NO:1 and described in the specification on page 4, lines 22 through 24.

Specific structure is further disclosed beginning on page 9, line 34 of the specification continuing through page 10, line 6, which reads: "These fragments will comprise at least about 20 contiguous nucleotides, preferably at least about 50 contiguous nucleotides, more preferably at least about 75 contiguous nucleotides, even more preferably at least about 100 contiguous nucleotides of the particular promoter nucleotide sequence disclosed herein. The nucleotides of such fragments will usually comprise the TATA recognition sequence of the particular promoter sequence."

Specific function is recited in the claims as: "...that drives transcription in a seed-preferred manner...." (Claim 1) and "...wherein the promoter initiates seed-preferred transcription...." (Claim 21).

Function is further described in the specification on page 9, on lines 33 and 34 which recite: "...those fragments...disclosed herein *that operate to promote the seed-preferred expression of an operably linked isolated nucleotide sequence*." And again on page 10, lines 16 and 17 which recite: "Such sequences encompass *fragments capable of driving seed-preferred expression...*".

The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "*reasonably* conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." (MPEP 2163.02).

By disclosing the foregoing identifying characteristics, it is believed that one of skill in the art would reasonably conclude that the applicant was in possession of the claimed invention. Accordingly, this rejection should be withdrawn.

Claims 1, 21, 40-41, and 44-45 are rejected under 35 U.S.C. §112, first paragraph because the specification does not reasonably provide enablement for claims broadly drawn to a functional fragment of the nucleotide sequence set forth in SEQ ID NO:1.

The Office Action states: "Applicants have not taught what is the function of the 'functional fragment' nor how one would assay the activity of the 'functional fragment'. In addition, Applicants have not provided guidance for how one skilled in the art would make and/or use the claimed 'functional fragment'."

Claims 1, 21, 44 and 45 have been amended to delete the word "functional".

The function of the presently claimed fragment is stated in the claims where it is recited: "An isolated *promoter that drives transcription in a seed-preferred manner...*". In addition, the function of the claimed fragment is described in the specification as cited herein in the argument for written description.

The assertion that Applicants have not taught how one would assay the activity of a functional fragment is without basis. The specification teaches the promoter::GUS assay in Example 3 on beginning on page 22. That this assay can

be used for any fragment to be tested is well known in the art and cited on page 11, lines 5-9.

Guidance as to how to make claimed fragments is found on page 10 of the specification, lines 6-13 which read: "Such fragments can be obtained by use of restriction enzymes to cleave the naturally occurring regulatory element nucleotide sequences disclosed herein; by synthesizing a nucleotide sequence from the naturally occurring DNA sequence; or can be obtained through the use of PCR technology. See particularly, Mullis *et al.* (1987) *Methods Enzymol.* 155:335-350, and Erlich, ed. (1989) *PCR Technology* (Stockton Press, New York). Again, variants of these fragments, such as those resulting from site-directed mutagenesis, are encompassed by the compositions of the present invention."

How to use the claimed fragments is described on page 11, lines 22-30 which recites: "The genes of interest expressed by the regulatory elements of the invention can be used for varying the phenotype of seeds. This can be achieved by increasing expression of endogenous or exogenous products in seeds. Alternatively, the results can be achieved by providing for a reduction of expression of one or more endogenous products, particularly enzymes or cofactors in the seed. These modifications result in a change in phenotype of the transformed seed. It is recognized that the regulatory elements may be used with their native coding sequences to increase or decrease expression resulting in a change in phenotype in the transformed seed."

The Office Action concludes: "....given the state-of-the-prior art which does not provide further guidance about Jip1 promoter regions and given the breadth of the claims which encompass a multitude of sequences that have not been exemplified, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention."

Promoter fragments that are functional equivalents of their longer counterparts were well known in the art at the time of filing. Kurek *et al* describes a wheat FK506-binding protein promoter that withstood an 873 bp deletion while

retaining essentially the same activity. (see Kurek *et al*, page 493, column 2, second paragraph; copy provided). Chen *et al* describes a 481 bp fragment deleted from a larger 4.4 kb promoter that retained "both spatial and temporal regulation of *PI* expression". (see Chen et al, page 86, bottom of column 2 under "Results"; copy provided).

A substantial number of promoter elements and motifs were known in the art at the time filing such that the skilled artisan could easily make rational choices to create a functional fragment from SEQ ID NO:1. Ezcurra *et al* describe at least 16 sequence elements conferring seed-specific expression in stable transformants. (See Ezcurra *et al*, page707, Table 1; copy provided). Wu *et al* describe promoter consensus regions associated with cereal storage proteins conferring endosperm-specific gene expression. (see Wu *et al*, page 416, Figure 1).

Making and characterizing functional promoter fragments is routine in the art. The Examiner cites Kagaya *et al* as an example of skill in the art. Kagaya describes fusing promoter fragments to GUS and transformed into plants to determine functionality of various promoter regions. Wu *et al* describe creating promoter fragments of the Glu B-1 gene, inserting these fragments into a GUS vector, transforming these into rice plants and analyzing GUS expression (see Wu *et al*, page 420, "Experimental procedures" section). Kurek *et al* fused wheat FKBP73 promoter fragments to luciferase (LUC) and measured the activity og the fragments relative to ubiquitin::GUS constructs bombarded into the same plant tissue (see Kurek *et al*, page 492, Figure 2). It is instructive that several of the fragments showed activity at or near the level of the promoter as a whole. Thus, making and characterizing functional promoter fragments by various methods was routine in the art at the time the application was filed.

The MPEP states: "Compliance with the enablement requirement of 35 USC 112, first paragraph, does not turn on whether or not an example is disclosed". (MPEP 2164.02, first paragraph).

It is respectfully suggested that: "It may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.'" *In re Grimme*, 274 F2d 949, 952, 124 USPQ 499, 501 (CCPA 1960).

It is submitted that the specification is fully enabling of present claims 1, 21, 40, 41, 44 and 45, and such that one of skill in the art could, without undue experimentation, isolate one or more nucleic acid molecules that: "...drive transcription in a seed-preferred manner....comprising a fragment of SEQ ID NO:1".

The entire breadth of the claims is supported by the specification as required under 35 USC §112, first paragraph. The specification provides methodology for isolating the promoter from a wide variety of plants and discloses the promoter region of Jip1 in SEQ ID NO:1 (see e.g. page 5, lines 14-26). The specification incorporates by reference commonly available methods for creating fragments encompassed by the present claims, such as: progressive deletions (page 10, line 32-page 11, line 9); exonuclease digestion (page 10, lines 20-31). Further provided are reporter genes for assaying promoter function such as GUS (β-glucoronidase) see page 17, lines 3-8.

In total, the specification provides sufficient guidance to one skilled in the art such that they could, through routine protocols, create a panel or library of Jip1 promoter fragments and test these fragments for Jip1 promoter activity so as to achieve Jip1 promoter fragments within the scope of claims 1, 21, 40, 41, 44, and 45.

The screening of panels or libraries containing from a few, to many, inoperative species in order to isolate one or more operative species is a common practice in many aspects of the biotechnological arts. Thus, it logically follows that the isolation of operative Jip1 promoter fragments from a panel or library of candidate promoter fragments is not undue experimentation where the Examiner has not put forth any evidence that the number of inoperative species would be significant and where one skilled in the art clearly has a reasonable expectation of

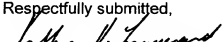
success in achieving Jip1 promoter fragments that are commensurate in scope with the present claims.

In view of the amendments and remarks, it is submitted that the rejections under 35 USC §112, first paragraph should be withdrawn.

CONCLUSION

On the basis of the above amendments and remarks, reconsideration of the application and its allowance are respectfully requested.

Respectfully submitted,



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